UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **THIS DOCUMENT RELATES TO:** *Track One Cases*	)	**MDL 2804** **Case No. 1:17-md-2804** **Judge Dan Aaron Polster** **OPINION AND ORDER DENYING MOTION TO EXCLUDE KELLER**

Before the Court is Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony **(Doc. #: 1914)**. For the reasons set forth below, the motion is **DENIED**.

I. Introduction.

Plaintiffs offer Keller's opinions to support their claims that the Manufacturers: (1) implemented inadequate suspicious order monitoring systems ("SOMS"); (2) failed to comply with the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq*. and its implementing regulations, 21 C.F.R. §§ 1301 *et seq*.; and (3) failed to investigate, report, and halt orders of prescription opioids into Summit and Cuyahoga counties which they knew, or should have known, were suspicious. *See* Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony ("Keller Response") at 1 (Doc. #: 2207). Plaintiffs also intend to apply Keller's opinions to causation issues to the extent she identifies suspicious orders, links these orders to physicians and pharmacies in Summit and Cuyahoga counties and, in turn, "demonstrates what would or could have occurred but for Defendants' failure to identify, report, and halt suspicious orders." *Id*. at 4.

To formulate her opinions, Keller analyzed several data sources containing information regarding distributors, prescribers, and purchasers of the Manufacturers' prescription opioids. After applying a series of analytical tools to each data source, Keller assessed matters such as whether the volume of opioids ordered or prescribed was over the limit identified by the applicable metric, whether a buyer significantly increased opioid prescriptions or purchases relevant to its own history, and how prescriptions and purchases compared to national averages for the Manufacturers' products. *See generally* Expert Analysis: Lacey R. Keller ("Keller Report") (Doc. #: 1914-4).

Based on her analysis, Keller concluded that, had Manufacturers utilized the data and analysis on which she relied—all of which she claims was available to them—they would have identified "millions of prescriptions and purchases of billions of dosage units and MMEs in Cuyahoga and Summit counties that defendant manufacturers of opioids (called labelers) could have identified as being of unusual size or frequency and deviating from the normal pattern yet were unreported." *Id*. at 9, ¶ 27. Keller further opined that:

> In the aggregate, suspicious orders that [Manufacturers] could have identified, but apparently did not, were responsible for *more than* half of all opioid prescriptions filled in Summit and Cuyahoga Counties in the periods 1997-2006 and 2008-2017, and for nearly half the MMEs dispensed there in the same time period. … [C]loser analysis of the flagged prescriptions would have confirmed that multiple identified doctors in Summit and Cuyahoga counties, not limited to those profiled in this report, were engaged in highly suspicious and likely improper prescribing. Similar, closer analysis of flagged pharmacies would have identified specific, identified (sic) highly problematic pharmacies. This analysis shows that it is and was possible to identify by name the problematic doctors and pharmacies in Summit and Cuyahoga counties in this period.

Id. at ¶ 35 (emphasis in the original).

Defendants seek to exclude Keller's opinions, arguing they are unreliable, would not assist the trier of fact, and would confuse the trier of fact.[1] Plaintiffs attack the reliability of various aspects of Keller's data, her methodology, her use of a hypothetical, and her analysis of certain Mallinckrodt "peculiar order" reports. For the reasons set forth below, the Court finds that Defendants' Motion must be denied.

II. Keller's Opinions.

A. The Data Keller Analyzed

Plaintiffs engaged Keller to perform "data mining." Data mining is "the practice of searching through large amounts of computerized data to find useful patterns or trends." https://www.merriam-webster.com/dictionary/data%20mining. Since November 2017, Keller has been employed by Gryphon Strategies, Inc., where she created, and is the managing director of, the data mining and analytics division. *See* Keller Report at 6, ¶ 1 (Doc. #: 1914-4). Prior to Gryphon, Keller was the director of research and analytics for the New York Attorney General, where she developed and managed the Community Overdose Prevention program using data analytics to determine how best to deploy naloxone, a medication used to block the effects of opioids, to law enforcement officers throughout the state. *See id*. at 6-7, ¶¶ 2-8. The chief dataset used by Keller for this work came from the DEA's Automation of Reports and Consolidated

[1] In their Reply in Support of Defendants' Motion, Defendants argue Keller's opinions do not "fit" the case and, therefore, are irrelevant. *See* Reply at 2-3 (Doc. #: 2471). Although they mention Rule 702's "fit" requirement in the "Legal Standard" portion of their Memorandum in Support of Defendants' Motion, Defendants fail to develop a "fit" argument in their initial briefing. The Court declines to address arguments raised for the first time in Defendants' reply brief. *See, e.g., Ross v. Choice Hotels Int'l, Inc.*, 882 F. Supp. 2d 951 (S.D. Ohio 2012) ("a reply brief is not the proper place to raise an issue for the first time") (citations omitted). Even if Defendants had addressed the relevancy and fit requirements mentioned in their Reply, the Court's conclusions would not change.

Orders System ("ARCOS"). *See id*. at 7, ¶ 8.

In the current case, Keller relied on several datasets to formulate her opinions (the "Keller Data"). The Keller Data is generally summarized below:

1. IQVIA Data: Much of Keller's analysis is premised on data compiled by, and available for purchase from, healthcare company IQVIA ("IQVIA Data"). IQVIA Data is submitted from pharmacies, mail order services, and long term care facilities and provides information about physicians and the drugs they prescribed. *See* Keller Report at 85-87, ¶¶ 159-164 (Doc. #: 1914-5). IQVIA Data is used, *inter alia*, to measure market and product demand and to track product demand over time. *Id*. at 85, ¶ 160. The IQVIA Data analyzed by Keller covered the period from 1997 through 2018, except for 2007 and the first four months of 2016. *See id*. at 85, ¶ 161. Keller opined that IQVIA Data was available to all Manufacturers; however, only a few of the Manufacturers who used the data for marketing purposes also used it for compliance purposes. *See id.* at 27-28, ¶¶ 76-80, Table 6. As of November 2017, IQVIA Data covered 93% of all prescriptions filled by retail pharmacies. *See id*. at 23, ¶ 72.

2. **ARCOS Data:** Keller also relied on information derived from ARCOS ("ARCOS Data"). ARCOS Data is typically used by government agencies to identify the diversion of controlled substances into illicit channels.[2] ARCOS traces the flow of controlled substances, like opioids, from manufacturer to distributor to hospital and pharmacy, and literally traces each opioid pill.[3]

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[2] *See* https://www.deadiversion.usdoj.gov/arcos/index.html.

[3] Keller used the ARCOS Data described in the report of Plaintiffs' expert Craig J. McCann with slight modification relating to the conversion of MMEs and Manufacturer's names. *See* Keller Report, at 85, ¶ 159.

3. Chargebacks and Other Sales Data: In addition to data from third-parties, Keller also analyzed data generated by Manufacturers themselves. This internal, transactional data, in large part, took the form of Chargebacks and "867" data. Chargebacks are requests for reimbursement submitted by distributors to Manufacturers when products are sold by the distributor for less than the distributor paid the Manufacturer. Information describing the drug prescribed, its dosage, and package quantity is contained in Chargebacks, which also can be used to obtain information about the purchasing patterns of Manufacturers' downstream customers, such as pharmacies. *See* Keller Report at 11, ¶ 33 (Doc. #: 1914-4). In addition, Manufacturers have internal sales data referred to as "867 data." 867 data informs a Manufacturer about the movements of its product downstream and may also detail returns.

B. The Metrics Keller Applied

Keller applied an assortment of compliance metrics to the Keller Data in an effort "to detect prescribing and purchasing patterns of unusual size, frequency, and pattern." (the "Keller Metrics"). Keller Report at 16, ¶ 51 (Doc. #: 1914-4). All but one of Keller's metrics were derived from metrics applied by a Manufacturer or a distributor. *Id*. If a transaction triggered a Keller Metric, it was "flagged." The Keller Metrics, their derivation, and the data to which they applied are described below. Ultimately, Keller describes 16 different metrics that, in her opinion, flag an opioid order as "suspicious."

1. Twice Trailing Twelve-Month Average ("Double National Average"): If, using

Chargebacks and IQVIA Data, the volume of transactions, dosage units, or MMEs[4] prescribed by a physician or purchased by a pharmacy within a calendar month exceeded twice the national average for other, similar pharmacies or physicians within the same month, the entity and its transactions were flagged. *See* Keller Report at 17, ¶ 55 (Doc. #: 1914-4). Keller applied this metric to all physicians and pharmacies. *Id.*

2. Three Times Trailing Twelve-Month Average ("Triple National Average"): This metric is essentially the same as the Double National Average metric but required the number of transactions, dosage units, or MMEs prescribed or purchased within a calendar month to exceed three-times the national average. *See id*. at ¶ 56.

3. McKesson 8,000 Rule: If, based on Chargebacks and IQVIA Data, more than 8,000 dosage units of oxycodone or hydrocodone were prescribed or purchased within a calendar month, the prescriber/purchaser was flagged. The methodology for this metric was derived from McKesson's "Lifestyle Drug Monitoring Program. *See id.* at 18, ¶ 57.

4. Maximum Monthly, Trailing Six-month Threshold ("Common Sense"): If, based on Chargebacks and IQVIA Data, an order, combined with other orders placed in the same 30-day period, requested more doses than the purchaser requested in any of the previous six calendar months, or if a product was ordered more frequently in a 30-day period than

[4] MME is an abbreviation for morphine milligram equivalents. The Centers for Disease Control published MME conversion factors that allow drugs to be compared to each other by converting various opioids with differing dosages into morphine milligram equivalents. *See* Keller Report (Doc. #: 1914-5, Ex. 2) at 87, ¶ 164.r.

it had been ordered by the purchaser in any of the previous six calendar months, these orders were considered deviations from previous trends and flagged. The methodology for this metric was derived from *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir 2017). *See id.* at ¶¶ 58-60.

5. Qualitest (Endo) 25%/50% National Average: If, based Qualitest's ARCOS data, a purchaser acquired 25% of the national average for a single drug code for retail pharmacies, or 50% of the national average for chain pharmacies, it was flagged. Keller applied this metric only to Qualitest. *See id*. at 18-19, ¶¶ 61-62.

6. Qualitest (Endo) 30,000 Rule: If, based on Chargebacks, an entity purchased more than 30,000 dosage units of hydrocodone in a month, it was flagged. This metric was applied to hydrocodone purchases from all Manufacturers. *See id*. at 19, ¶ 63.

7. Mallinckrodt: Rolling Average (Double): Using Chargebacks, Keller flagged purchases within a 30-day period that were double the buyer's average purchases over the previous 18 months. Average purchases were evaluated both for order quantity and order frequency and customers were compared to their own order histories. This metric was derived from Mallinckrodt's SOMS and was applied to all Defendants. *See id*. at 19-20, ¶ 64.

8. Mallinckrodt: Rolling Average (Triple): This metric is essentially the same as the Mallinckrodt Rolling Average (Double) metric but required purchases within a 30-day period to acquire triple the buyer's average purchases over the previous 18 months. *See id*. at 20,

¶ 65.

9. Actavis (Teva): 125% Order Average: Using Chargebacks, Keller flagged any buyer that placed a single order that was 125% of its previous six-month average order of a specific product. This metric does not focus on the aggregate volume for a customer but, instead, looks at single orders. *See id*. at 21, ¶ 68.

10. Teva: Three Standard Deviations: Based on Teva's SOMS system in effect from approximately 2012 to 2015, and using each Defendant's Chargebacks, Keller flagged orders (by volume) that were more than three standard deviations above a purchaser's monthly mean, calculate approximately twice per year. *See id*. at 21-22, ¶¶ 69-70.

11. Multiple Distributors: To avoid situations in which pharmacies bought opioids from multiple distributors, in order to evade individual distributor compliance thresholds, Keller flagged pharmacies that purchased the same drug formulation (drug family and dosage strength) from two or more distributors within one calendar month. *See id*. at 22, ¶ 71.

12. 50% Six-Month Increase: If, using IQVIA Data, a prescriber's average monthly prescription total for a current six-month period increased by more than 50% compared to the average monthly prescription total for the preceding six-month period, the prescriber was flagged. This metric was included in Purdue's internal SOMS. *See* Keller Addendum at 26 (Doc. # 2207-1).

13. 75% High Dosage: Using IQVIA Data, and based on Purdue's SOMS, any prescriber who prescribed a "large concentration of particular strength prescriptions" was flagged. *Id.* For example, a prescriber who wrote more than 75% of her prescriptions for OxyContin 40mg and/or OxyContin 80mg within a calendar month was flagged by this compliance metric. *Id.*

14. State Average Overall Volume: Based on a metric derived from Purdue documents, Keller flagged any purchaser whose total transactions for a particular drug type was greater than one standard deviation above the statewide per-purchaser average for the same drug type. Purchasers were grouped by business activity. As a result, statewide per-purchaser averages were calculated separately for chain pharmacies, retail pharmacies, and practitioners. Total transactions were measured as the total of 867 and ARCOS Data, dosage units, and MMEs and metrics were calculated over three, six, and twelve month periods. *Id.* at 30.

15. State Average Percent of Volume: This metric was virtually identical to the State Average Overall Volume metric but flagged purchasers whose percentage share of the state's total volume of a particular drug type was greater than one standard deviation above the statewide per-purchaser average for the same drug type. *Id.* at 30.

16. State Average Highest Dosage: Based on a metric derived from Purdue documents, Keller flagged any pharmacy whose proportion of the highest dosage available per drug type out of all opioid volume was more than one standard deviation above the statewide per-purchaser average. *Id.* at 30.

C. The Conclusions Keller Reached

After applying the Keller Metrics to the Keller Data, Keller offered a number of opinions, including those summarized below.

1. If Manufacturers had applied standard, available analytic tools to the IQVIA Data, they would have discovered suspicious prescribing activity by thousands of Summit and Cuyahoga county physicians.[5]

Relying on IQVIA Data and the Keller Metrics, Keller flagged thousands of Summit County and Cuyahoga County physicians who wrote suspicious opioid prescriptions. *See* Keller Report at 29-30, ¶ 81 (Doc. #: 1914-4). To validate her conclusions, Keller provided data from Purdue, Endo, and Mallinckrodt identifying doctors as suspicious that she too identified as having written suspicious prescriptions. Keller also compiled six prescriber case studies detailing the extraordinary number of opioid prescriptions written by these few doctors, the products they prescribed, and the numerous sales calls made on these physicians by various of the Manufacturers. *See id*. at 31-53, ¶¶ 82-112.

2. If a single small labeler had reported suspicious activity, prescriptions for millions of flagged dosage units could have been stopped.

Janssen had the second smallest market share of opioids prescribed in Summit and Cuyahoga counties. Keller hypothesized about the impact Janssen would have had if it identified and reported orders that triggered a compliance metric. More specifically, Keller assumed Jansen

[5] Plaintiffs represent that Keller will not offer any opinions concerning: whether any Manufacturer's SOMS complied with the CSA; whether Manufacturers should have used the Keller Metrics as part of their SOMS; that any order flagged by the Keller Metrics should have been reported to the DEA; or that any order flagged by the Keller Metrics was inherently "suspicious" pursuant to the CSA. The Court will take Plaintiffs at their word and will not allow any such opinion testimony from Keller at trial, as these are matters for the jury.

flagged prescribers identified by IQVIA-based metrics. She also assumed Janssen reported the flagged prescribers to regulatory authorities and the authorities prevented the flagged doctors from writing further opioid prescriptions "at the earliest indication of irregular behavior." Keller Report at 53-54, ¶¶ 113-114 (Doc. #: 1914-4).

Based on these assumptions, Keller concluded that Janssen could have stopped as many as 15% of all opioid prescriptions written in Summit and Cuyahoga counties between 1997 and 2017 and could have precluded hundreds of physicians from writing opioid prescriptions during this period. *See id*. at 53-55, ¶¶113-116.

3. If Manufacturers had applied standard, available analytic tools to their internal data, they would have discovered and reported suspicious pharmacy activity in Summit and Cuyahoga counties preventing hundreds of millions of dosage units from being dispensed there.

Relying on Chargebacks and 867 data, Keller identified pharmacies in Summit County and Cuyahoga County whose purchase activity was flagged by one or more of the Keller Metrics. In addition, Keller identified the number of transactions, the number of dosage units represented by Chargebacks, and which Manufacturers were associated with the flagged transactions. *See* Keller Report at 58-63, ¶¶ 124-127 (Doc. #: 1914-4). To validate her conclusions, Keller provided six pharmacy case studies describing the extraordinary number of opioid prescriptions filled by these few pharmacies. *See id*. at 63-82, ¶¶ 128-153.

4. Had Mallinckrodt reported the orders it classified as "peculiar," thousands of doses of prescription opioids would not have made their way to Summit and Cuyahoga counties.

Documents produced during discovery revealed that Mallinckrodt—using its own internal metrics—identified more than 58,000 "peculiar" opioid purchases made by distributors and sent

to distribution centers throughout the country. *See id*. 83, ¶ 154. None of these distribution centers were in Summit or Cuyahoga counties. *See id*. at ¶ 156. To determine whether any of these "peculiar" Mallinckrodt orders ended up in the bellwether counties, Keller used Mallinckrodt Chargebacks to identify Summit and Cuyahoga buyers that purchased an opioid product from a distributor within thirty days (before or after) the date that distributor was flagged as "peculiar" by Mallinckrodt for a transaction involving that same opioid product. *Id*. Keller opined that Mallinckrodt's Chargebacks allowed it to determine where its orders were shipped and, based on her analysis, she concluded nearly 2,900 "peculiar" transactions were connected to Summit or Cuyahoga counties. *See id*. at 84, ¶ 158.

III. Defendants' Motion to Exclude Keller.

Defendants complain that Keller's opinions are unreliable, would not assist the trier of fact, and would confuse the jury because: (a) Keller's methodology used to identify "suspicious orders" does not employ the methodology of the Controlled Substances Act and does not consider the effect of due diligence; (b) Keller's Jansen opinion is premised on a hypothetical analysis divorced from actual events; (c) Keller's prescriber ad small labeler opinions are unreliable because the IQVIA Data on which Keller relies is unreliable; and (d) Keller's Mallinckrodt opinion is based on the unsupported assumption that, if Mallinckrodt identified a distributor's order as "peculiar," then bottles of the same product sold to pharmacies by that distributor within thirty-days of discovery of the peculiar order were part of the earlier "peculiar" order. Each of these arguments is addressed below.

A. Keller's Methods for Identifying Flagged Orders Is Unreliable and Would Mislead the Jury.

1. Keller's flagged orders do not constitute "suspicious orders" as that term is used in the CSA.

Defendants argue that the orders flagged by Keller do not constitute "suspicious orders" as that term is used in the CSA and, therefore, her options are unreliable and would confuse the jury. *See* Defendants' Memorandum in Support of Defendants' Motion ("Defendants' Memorandum") at 5-7 (Doc. #: 1914-1). Defendants also argue that Keller's reference to an order being "suspicious" simply means the order triggered one or more of the Keller metrics and neither Plaintiffs' experts nor any DEA witness testified that, if an order triggers a Keller metric, it is *necessarily* "suspicious." *See id*. at 6. Based on the provisions of the CSA and the regulations implementing it, the Court disagrees that this argument is sufficient to prevent the jury from hearing Keller's testimony.

DEA regulation 21 C.F.R. § 1301.74(b) does not define precisely what constitutes a "suspicious order." However, it makes clear that "suspicious orders" include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." The Keller Metrics seek to identify exactly that: each metric addresses whether an order or series of orders is distinctive as to size, frequency, or pattern when compared to other orders by the purchaser/prescriber, national orders of like-kind, state orders of like kind, or otherwise. This analysis fits snuggly within what the CSA anticipates, and Keller's report notes as much. *See* Keller Report at n. 23 (Doc. #: 1914-4). Also compelling is that most of the Keller metrics were derived from the Manufacturer's own algorithms. As this Court has previously found, an order may be suspicious for any number of reasons, and there are many metrics available to identify opioid orders as suspicious. *See* Discovery Ruling No. 12 ("DR-12") at 2-3, n.2 (Doc. #: 1174). Defendants assert Keller has overreached in her design and application of the Keller Metrics to

identify suspicious orders, but Defendants will have the opportunity for "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Burgett v. Troy–Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)).

Furthermore, the Court has assessed the potential for Keller's opinions to unfairly prejudice, confuse, or mislead the jury. *See* FED. R. EVID. 403. In conducting this exercise, the Court has looked at "the evidence in the light most favorable to the proponent, maximizing its probative value and minimizing its prejudicial effect." *United States v. Smith*, 736 F.2d 1103, 1107 (6th Cir. 1984). Given the scope and complexity of the other expert testimony and evidence to be heard at trial, the court finds that any such potential confusion is low and certainly not outweighed by the probative value to the jury of Keller's "number crunching." To the contrary, Keller's opinions regarding the metrics available to the Manufacturers and her application of these metrics to the Keller Data is relevant and helpful to the trier of fact. For example, her testimony will assist the jury in deciding: (1) whether Manufacturers employed reasonable measures to identify potentially suspicious orders; and (2) the number of orders Manufacturers could have flagged if they had employed these measures. And the Manufacturers, of course, may counter that: (a) the Keller Metrics were not appropriate for them; or (b) their own metrics, though different from Keller's, were sufficient or equally effective.

That Keller does not opine as to whether a Manufacturer should have used some or all of the Keller Metrics as part of its SOMS, that any order identified by the Keller Metrics should have been reported to the DEA, or that any order flagged by the Keller Metrics was inherently "suspicious" pursuant to the CSA, does not alter the Court's analysis. *See* Defendants' Memorandum at 6 (Doc. #: 1914-1). If these omissions are flaws in Keller's analysis, Defendants

will have the opportunity to identify and develop these deficiencies through cross examination and the proffer of their own experts. "The *Daubert* standard is liberal, and does not require expert opinions to be bulletproof." *U.S. v. Lang*, 7717 Fed. Appx. 523, 534 (6th Cir. 2017). Instead, the Supreme Court prefers that litigants rely upon "the capabilities of the jury and of the adversary system generally," rather than "wholesale exclusion" of fairly supported, relevant testimony by the Court. *In re Welding Fume Products Liab. Litig.*, No. 1:03-CV-17000, MDL 1535, 2005 WL 1868046, at *5 (N.D. Ohio Aug. 8, 2005) (quoting *Daubert*, 509 U.S. at 596).

Defendants also find fault with Keller's application of the same metrics to each Manufacturer without regard to whether the Manufacturer actually used the metric. *See* Defendants' Memorandum at 7 (Doc. #: 1914-1). Defendants emphasize that a registrant's SOM program should be tailored to its "particular business model and medications" and "[e]ven if a particular criterion is used by one manufacturer for its internal analysis, there is no reason to believe that such a metric would be appropriate for another manufacturer." *Id.* This is true; however, this argument goes to the weight of Keller's testimony, not to whether it is admissible. If Manufacturers could have applied an available metric to detect suspicious orders and then reported those orders to the DEA as anticipated by 21 C.F.R. § 1301.74(b), then this is relevant to the jury's analysis of the Manufacturer's actions and should be presented to them for their consideration.

2. Keller's opinions should be excluded because her metrics do not consider the impact of Manufacturer due diligence.

Defendants argue that, even if an order is flagged as potentially suspicious, it may be determined through due diligence that the order need not be reported to the DEA because the suspicion is dispelled. *See* Defendants' Memorandum at 7-8 (Doc. #: 1914-1). They complain

Keller failed to assess how "each order was processed, monitored, flagged, unflagged, or released et cetera" and, therefore, her analysis is unreliable because it fails to consider how flagged orders were impacted by the Manufacturers' due diligence. *Id.*

Plaintiffs respond to this argument by discussing whether an order is actually suspicious only after due diligence has been performed, or if the "suspicious" label attaches immediately upon discovery. Relying on language from *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017), a 2007 letter from the DEA, and witness testimony, Plaintiffs assert that the "suspicious" label and the requirement to report attach immediately upon discovery and, therefore, due diligence is not relevant to the labeling of an order as "suspicious." *See* Keller Response at 9-10 (Doc. #: 2207). The Court need not decide this issue here.[6]

First, the Court notes Keller does reference due diligence in her report, stating:

> Every month, metrics were re-applied so that an entity (i.e., physician, pharmacy) that was flagged in the previous month was not flagged by default in the following month. This provided a lower estimate of the number of physicians or pharmacies that were flagged by each compliance metric and gave the manufacturer credit as if due diligence was performed on that entity in that month.

Keller Report at 16, ¶ 53 (Doc. #: 1914-4). Moreover, in the Addendum to her report, she re-analyzes her data without the due diligence assumptions. *See* Keller Addendum at 9 (Doc. # 2207-1). Even if this were not the case, whether Keller did or did not properly account for the impact, if any, of due diligence, speaks to the weight of Keller's testimony and not its admissibility. Keller uses her metrics to identify suspicious orders and does not opine that due diligence could *not* then dispel this suspicion. The point is that Keller's Metrics identify orders that, in her opinion, at a

[6] The Special Master previously noted that the law is unclear as to *when* the order is deemed "suspicious" and the duty to report arises. DR-12 at 4-7 (Doc. #: 1174) (noting conflicting statements in *Masters II*). More specifically, it is unclear whether a suspicious order must be reported immediately, *i.e.* before a registrant investigates, or afterwards, *i.e.* only if the investigation fails to dispel the suspicion. *Id.*

minimum require due diligence. Accordingly, the Court rejects Defendants' due diligence argument.

B. Keller's opinion relating to Jansen is unreliable and should be excluded because it is premised on a hypothetical analysis and divorced from actual events.

In Keller's opinion, "if Janssen—the defendant labeler with the second smallest market share in Summit and Cuyahoga counties—had reported suspicious activity, prescriptions for millions of dosage units could have been stopped in Summit and Cuyahoga counties." Defendants' Memorandum at 8 (Doc. #: 1914-1) (quoting Keller Report at 11, ¶ 34 (Doc. #: 1914-4)).

Defendants criticize this opinion not only for the reasons described above, but also because they claim it assumes "each prescriber would have been stopped from prescribing all opioids immediately after his or her first prescription was reported to law enforcement and immediately after being flagged by any of Keller's 16 criteria." Defendants' Memorandum at 9 (emphasis omitted) (Doc. #: 1914-1). Defendants attach evidence supporting their argument that revocation of prescribers' DEA licenses and other enforcement actions are not instantaneous and diversion investigations take significant time. *Id.* They conclude Keller's failure to consider the "real world" implications of her analysis renders her opinions unreliable and would mislead the jury. *Id.*

In response, Plaintiffs emphasize that Keller's opinion as to Jansen was in response to a hypothetical and, therefore, admissible. *See* Keller Response at 14 (Doc. #: 2207). Although they assert that, at trial, they will introduce evidence that proves-up the assumptions underlying the hypotheses on which this opinion is based, they fail to provide this evidence with their response. *Id*.

"Clearly, it is proper for a party to pose hypothetical questions to experts." *United States v. McCafferty*, 801 F.Supp. 2d 605, 621 (N.D. Ohio 2011) (citing *Jackson v. A–C Prod. Liab.*

Trust, 622 F.Supp. 2d 641, 646 (N.D. Ohio 2009)). Counsel may ask a hypothetical question as long as the question sets forth its factual assumptions. *McCafferty*, 801 F.Supp. 2d at 621 (citing *Collins v. Penn Const. Transp.*, 487 F.2d 1296, 1298 (2d Cir 1974)). Hypothetical questions should be "an accurate summation of the evidence already presented in the record and can neither add nor distract from that evidence." *Myers v. Weinberger*, 514 F.2d. 293, 294 (6th Cir. 1975) (reversing judgment for defendant in a disability case where defendant failed to present evidence, other than in the form of a hypothetical question, that plaintiff was able to perform another job). If the party positing the hypothetical fails to independently prove the facts assumed, the jury is free to disregard the conclusion of the witness. *McCafferty*, 801 F.Supp. 2d at 621.

At this stage of the proceedings, the Court declines to strike Keller's opinions relating to Janssen and the impact Manufacturers with small market shares could have had on the number of opioids in the bellwether Plaintiff counties. However, at trial, prior to the introduction of Keller's testimony on this topic, the Court will require Plaintiffs to clearly articulate the assumptions underlying their hypothetical(s) and establish that their hypothetical(s) present an accurate summation of the evidence present in the record.

C. The IQVIA Data on which Keller relies to support her opinions is unreliable.

Plaintiffs take issue with Keller's opinions based on the IQVIA Data, arguing these opinions are unreliable because Keller does not know whether the Manufacturers had the same set of IQVIA Data on which she relied. Defendants' Memorandum at 10 (Doc. #: 1914-1). More specifically, the Manufacturers note Keller used IQVIA data purchased by Allergan in 2018 and assumed the Manufacturers could have (but were not obligated to) purchased IQVIA for the 20-year period addressed in her report. *Id*.

Defendants also complain that: (a) "IQVIA data is dynamic, changing year to year to reflect changes in the landscape of information it encompasses;" (b) and "IQVIA does not maintain historical order information for past opioid-related purchase in the ordinary course of business or copies of historic data deliverables... *Id*. at 11. Therefore, they argue, the 2018 data Keller used for her analysis, and her opinions derived from that analysis, are unreliable. *Id*.

In response, Plaintiffs emphasize that the Manufacturers had access to IQVIA's data during the relevant time period and that many of them purchased and relied upon this data for marketing and other purposes. *See* Keller Response at 11-12 (Doc. #: 2207). They also argue that any dispute about IQVIA's ability to create identical data sets goes to the weight, not the admissibility of this evidence. *Id.*

There is no real dispute that the Manufacturers had, or had access to, IQVIA data *as it was being collected* and that IQVIA's data is the best third-party evidence available to show the path the Manufacturers' opioid products took after they left the Manufacturers' control. The historical dataset Keller used was not meaningfully different from what Manufacturers had access to, in real time, in smaller increments. Although each dataset may result in an incremental difference in the specific number of prescriptions or shipments, these differences are inconsequential to Keller's ultimate opinion that, if Manufacturers had used the data and analysis available to them, they would have identified as unusual "millions of prescriptions and purchases of billions of dosage units and MMEs in Cuyahoga and Summit counties." The Court will not strike Keller's opinions based on Defendants' challenge to the IQVIA dataset used by Keller, and will allow the jury to hear Keller's testimony and decide how much weight it deserves.

D. Keller's opinion that, if Mallinckrodt identified a distributor's order as "peculiar," then bottles of the same product sold to pharmacies by that distributor within thirty-days of discovery of the "peculiar" order were part of the "peculiar" order is unreliable.

Mallinckrodt's internal algorithms identified more than 58,000 "peculiar" purchases made by distributors. These purchases were sent to distribution centers throughout the country. None of the distributors or distribution centers were in Summit or Cuyahoga counties and there is no specific data identifying one way or the other where the "peculiar" orders were eventually shipped.

To determine if any "peculiar" Mallinckrodt orders were sold in Summit or Cuyahoga counties, Keller devised a metric that purportedly traced the distributors' shipments back to "peculiar" orders placed with Mallinckrodt. *See* Keller Report at 83-84 (Doc. #: 1914-4). Keller's metric is based on the assumption that any shipment by a distributor made within 30 days (before or after) that distributor placed a "peculiar" order to Mallinckrodt was necessarily fulfilled with bottles shipped by Mallinckrodt in response to the distributor's "peculiar" order. *Id*. at 83. Put another way, "[i]n estimating what portion of a "peculiar" orders found their way to Summit and Cuyahoga Counties, Keller's (sic) assumed that purchases by pharmacies in Summit and Cuyahoga made in reasonable temporal proximity to a "peculiar" order came from that order." Keller Response at 13 (Doc. #: 2207).

Applying this metric, Keller opines that there were approximately 2,900 shipments into Summit and Cuyahoga counties that "involved distributors that shipped the same opioid product purchased in the peculiar transaction to buyers in either Summit County or Cuyahoga County within 30 days." *Id*. at 84.

Defendants argue that Keller's tracing assumptions are arbitrary and unsupportable and her use of Chargeback data in this context is misplaced. *See* Defendants' Memorandum at 12-13 (Doc. #: 1914-1). To support their position, they offer the report of their own expert, Edward J. Buthusiem, who attacks Keller's assumptions and methodology, concluding that: "…there is no way to trace a chargeback to the distributor's original purchase from the manufacturer. Even

assuming, *arguendo*, that her analysis is not fundamentally flawed in that regard, however, Ms. Keller's results are nonetheless incorrect, overstated, and unreliable because she employs unsupported assumptions and incorrectly applies her own methodology." Buthusiem Report at 7 (Doc. #: 1914-15). And, after correcting for Keller's alleged errors, Buthusiem opines: "…even adjusting her flawed logic reduces the peculiar orders she incorrectly traces to the Counties by 56% to 60%." *Id*. at 12.

Defendants also rely on Keller's testimony acknowledging limitations on her then-current analysis, her lack of knowledge about the use of Chargeback data, and her lack of information about distributor inventory practices. *See* Keller Response at 12-13 (Doc. #: 2207). For example, Keller testified as follows:

> Q. So you don't know if, for example, if a distributor purchases places an order (sic) with Mallinckrodt for one of its products, you don't know if – and Mallinckrodt ships it to that distributor, the product that was purchased, you don't know if the distributor would have other of Mallinckrodt's products already in its inventory at the time it places that order?
>
> A. Correct. I'm not an expert in supply chain, nor am I an expert in distributor LIFO or any of their practices there, nor do I -- you had another point in there, but, no, that would be outside of my expertise. Actually, nor was I given data on those practices.

June 13, 2019 Deposition of Lacey R. Keller at 366:2-17 (Doc. #: 1914-2).

Plaintiffs defend Keller's analysis relying on her testimony explaining that her use of a 30-day period was reasonable because many of the SOMS algorithms use a 30-day lookback period and Chargebacks were submitted by some distributors on a monthly basis. *See* Keller Response at 12 (Doc. #: 2207). Plaintiffs also assert that, even though Keller does not know exactly how many pills in a peculiar order found their way to Summit and Cuyahoga counties, "information regarding the number of peculiar transactions that involved distributors that shipped the same opioid product purchased in the peculiar transaction to buyers in Summit and Cuyahoga Counties

within 30 days is relevant and will assist the trier of fact. *Id*. at 12-13. Plaintiffs also provide case law purporting to support the argument that it is permissible for an expert to rely on reasonable assumptions and to extrapolate an estimate. *See* Keller Response at 13 (Doc. #: 2207).

It is undisputed that Keller is not an expert in matters relating to how distributors operate their businesses and relied on information provided to her in applying her analytics and formulating her conclusions. Defendants' expert disagrees mightily with Keller's assumptions and analysis, offering a very different version of the facts relating to Chargebacks and how distributors operate. But even Defendants' expert acknowledges that some number of the Mallinckrodt "peculiar" orders travelled to Summit and Cuyahoga counties, even if this number is substantially smaller than Keller opines. Ultimately, Keller's assumptions are not so unreasonable that her analysis must be excluded.

There may indeed be flaws in Keller's extrapolations concerning Mallinckrodt's "peculiar" orders so that her opinions are rejected in whole or in part by the jury. However, the Court may not exclude an "expert's testimony on the ground that the court believes one version of the facts and not another." *In re Scrap Metal Antitrust Litig.,* 527 F.3d 517, 529 (6th Cir. 2008) (quoting Federal Rule of Evidence 702 advisory committee's note, 2000 amend.). Challenges to the accuracy of an expert's conclusions or the factual bases underlying her opinion generally "bear on the weight of the evidence rather than on its admissibility." *United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir.1993). Accordingly, the Court will allow the jury to hear the evidence offered by Keller and to decide this "battle of the experts."

In sum, Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony (Doc. #: 1914) is **DENIED.**

IT IS SO ORDERED.

/s/ Dan Aaron Polster ***August 20, 2019***
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE